

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )  
 ) MDL No. 13-2419  
 ) Dkt. No 1:13-md-2419 (RWZ)  
\_\_\_\_\_)  
THIS DOCUMENT RELATES TO: )  
 )  
All Cases Against the Saint Thomas )  
Entities )  
 )  
\_\_\_\_\_)

**SAINT THOMAS ENTITIES' STATEMENT OF UNDISPUTED, MATERIAL FACTS  
IN SUPPORT OF THEIR GLOBAL MOTION FOR PARTIAL SUMMARY  
JUDGMENT ON CLAIMS FOR ACTUAL AGENCY AND DIRECT LIABILITY**

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.1, the Saint Thomas Entities<sup>1</sup> file this Statement of Undisputed, Material Facts in Support of their Global Motion for Partial Summary Judgment on Claims for Actual Agency and Direct Liability as to the MDL Plaintiffs bringing claims against them.

**STATEMENT OF UNDISPUTED, MATERIAL FACTS**

1. Howell Allen Clinic has at all relevant times employed the persons who decided to purchase medicine from NECC, namely Dr. Culclasure (STOPNC's Medical Director) and Nurse Schamberg (STOPNC's Facilities Director). *See* February 5, 2015, Deposition of Scott Butler ("Butler I Depo."), attached as Exhibit A, at 53:2-54:8; September 17, 2015, Deposition of Scott Butler ("Butler II Depo."), attached as Exhibit B, at 16:21-24; 113:1-8. These individuals reported

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<sup>1</sup> Saint Thomas West Hospital, formerly known as St. Thomas Hospital ("Hospital"), Saint Thomas Network ("Network"), and Saint Thomas Health ("Health") (collectively, the "Saint Thomas Entities").

to Howell Allen Clinic's President and Chief Administrative Officer, respectively. *See* Exhibit B at 16:25-17:4.

2. In 2012, Health wholly owned five hospitals and a number of physician practices and rehabilitation facilities. April 6, 2015, Deposition of Michael Schatzlein, M.D. ("Schatzlein I Depo."), attached as Exhibit C, at 21:18-22:3. Network, a wholly owned subsidiary of Health, had an ownership interest in a number of joint ventures, including STOPNC. *Id.* 22:3-22:6.

3. Health is a non-profit corporation organized under the laws of Tennessee. July 2, 2015, Deposition of Dawn Rudolph ("Rudolph II Depo."), attached as Exhibit D, at 19:15-20.

4. Network and Hospital are also non-profit corporations organized under Tennessee law. *Id.* 17:19-24. Network is essentially a holding company for joint-venture investments. July 21, 2015, Deposition of Michael Schatzlein, M.D. ("Schatzlein II Depo."), attached as Exhibit E, 74:7-24; 79:5-19.

5. STOPNC is a Tennessee limited-liability company owned 50% by Network and 50% by Howell Allen Clinic, a professional association of physicians. Exhibit A at 25:8-16; Exhibit B at 24:13-21; Exhibit E at 72:6-19. STOPNC is a joint-venture investment of Network. Exhibit C at 19:6-9; *see also* Apr. 21, 2015, Deposition of Dawn Rudolph ("Rudolph I Depo."), attached as Exhibit G, at 19:14-23.

6. The parties to the Operating Agreement for STOPNC are Saint Thomas Health Services and "Neurosurgical Surgeons, P.C." Saint Thomas Neurosurgical Center, LLC Operating Agreement (July 1, 2000) ("Operating Agreement"), attached as Exhibit F. Saint Thomas Health subsequently became Network, and the successor to Neurosurgical Surgeons, P.C. is Howell Allen Clinic. Exhibit E at 69:19-22; 76:2-9; *see also* Exhibit B at 26:6-8.

7. The STOPNC board has habitually observed its corporate governance requirements, holding regular board meetings and keeping corporate minutes. Exhibit B at 42:1-24. Ms. Schamberg is responsible for maintaining the minutes. *Id.* at 42:20-24.

8. Under the agreement that defines their rights as owners, Howell Allen Clinic and Network each have the right to appoint two members of the Board of Governors of STOPNC. *See* Exhibit F at § 7.2; *see also* Exhibit C at 30:16-19; Exhibit A at 28:16-24; *see also* Exhibit F at § 7.1. The Network appointments to the STOPNC Board were Craig Polkow (then-CFO of Saint Thomas Health) and Dale Batchelor, M.D. (then-Chief Medical Officer of Hospital), and for a short period, Dawn Rudolph (then-Chief Executive Officer of Hospital). Exhibit G at 21:15-25; 23:20-24:1; 80:5-8. Network's appointments to the STOPNC Board were all highly regarded professionals with significant experience in the healthcare setting. *Id.* at 17:5-14; 91:21-24; September 2, 2015, Deposition of Dale Batchelor, M.D. ("Batchelor Depo."), attached as Exhibit H at 9:15-11:1-12.

9. Pursuant to the Operating Agreement and their fiduciary duties as board members, the board of STOPNC appointed managers to run the business. Exhibit F at §§ 7.1, 8.1. It also approved a services agreement with Howell Allen Clinic to provide all of the STOPNC employees and the Medical Director. *See* Services Agreement between Neurological Surgeons, P.C. (n/k/a Howell Allen) and STOPNC ("HAC-STOPNC Services Agreement"), attached as Exhibit I; *see also* Sept. 27, 2007 Addenda to Services Agreement (STOPNC\_0713-14), attached as Exhibit J (Howell Allen was to assume the "Medical Directorship," "Provide direction and leadership for the Medical Staff," "Monitor quality assurance and patient care," and "Provide all staff."); Exhibit B at 25:18-26:8; 29:22-30:22; Exhibit E at 77:1-3.

10. STOPNC was managed by Howell Allen Clinic pursuant to the written management agreement, and Howell-Allen employees fulfilled the roles of Medical Director and Facilities Director, charged with overseeing the day-to-day operations of STOPNC—including procurement decisions such as where to buy medication—and reporting directly to Howell Allen Clinic management. Exhibit I; *see also* Exhibit G at 101:17-24; Exhibit H at 30:17-31:14; July 15, 2015, Deposition of Rebecca Climer (“Climer II Depo.”), attached as Exhibit K, at 75:4-20; Exhibit A at 53:2-54:8; Exhibit B at 16:25-17:4; 113:1-8. The STOPNC board members understood their role, as defined under the Operating Agreement, as being “an oversight of the . . . financial affairs of STOPNC,” while “the business and the operations of the STOPNC were under [the] management agreement . . . .” Exhibit G at 101:17-24.

11. At the time of the meningitis outbreak in 2012, STOPNC’s Medical Director was Dr. Culclasure, and its Facilities Director was Nurse Schamberg. March 23, 2015, Deposition of John W. Culclasure, M.D. (“Culclasure Depo.”), attached as Exhibit L, at 14:21-23; 15:5; February 4, 2015, Deposition of Debra Schamberg, R.N. (“Schamberg Depo.”), attached as Exhibit M, at 28:1-4. As Facilities Director, Nurse Schamberg oversees the day-to-day activities of STOPNC—“the staff and the running of the facility, anything that’s a part of the clinical side.” Exhibit M at 28:1-12.

12. STOPNC is located on what is known as the St. Thomas Hospital campus. Exhibit C at 38:2-4. The medical office building in which STOPNC is located is owned by HRT, a real estate company that is not affiliated in any way with the Saint Thomas Entities. Exhibit E at 100:19-25. Howell Allen Clinic (or its predecessor) is the tenant on the STOPNC lease. Exhibit A at 166:17-167:4. Howell Allen Clinic also handles the billing for STOPNC and collects the

money for patient procedures performed by STOPNC, including the epidural steroid injections (“ESIs”) that contained the NECC-compounded MPA. Exhibit L at 67:4-24; 194:25-195:3.

13. All of STOPNC’s patients are referred by Howell Allen Clinic doctors. September 18, 2015, Deposition of Gregory B. Lanford, M.D. (“Lanford Depo.”), attached as Exhibit N, at 68:22-69:11; Exhibit L at 153:21-22. And if the steroid injections provided by STOPNC are not successful in resolving the patient’s pain, then these patients may be referred back to the Howell Allen Clinic neurosurgeons for further treatment. Exhibit C at 33:11-21.

14. The responsibility for purchasing medications for STOPNC patients resided solely with Nurse Schamberg in consultation with Dr. Culclasure. Exhibit B at 113:9-16. Neither Hospital nor Health nor Network has ever supplied medicines or pharmaceutical procurement services for STOPNC. Exhibit D at 69:24-70:5; August 21, 2015, Deposition of Carmen Leffler (“Leffler Depo.”), attached as Exhibit O, at 105:19-106:11; 115:17-116:7; August 26, 2015, Deposition of Martin Kelvas (“Kelvas Depo.”), attached as Exhibit P, at 180:9-18. STOPNC was not subject to any policies or requirements of Health or Hospital regarding medicines. Exhibit P at 65:20-66:16; 68:1-10.

15. None of the Saint Thomas Entities had any involvement with the decision of Dr. Culclasure and Nurse Schamberg to purchase MPA from NECC. Exhibit M at 237:4-9. While Hospital has its own pharmacy, it was not responsible for purchasing medications for STOPNC and has never supplied pharmaceuticals, medical supplies, or procurement services to STOPNC. Exhibit D at 69:24-70:5; Exhibit O at 105:19-106:11; 115:17-116:7; Exhibit P at 180:9-18; *see also* Exhibit M at 174:20-175:3. Hospital is a completely separate entity from STOPNC. Exhibit N at 126:13-21; *see also* Exhibit M at 30:19-20 (“St. Thomas Hospital had nothing to do with my job . . .”). None of the Saint Thomas Entities had any involvement whatsoever in overseeing

STOPNC's pharmaceutical practices, including setting policies as to what medications STOPNC would procure and provide to its patients. Exhibit C at 96:13-23; 148:17-22; Exhibit E at 40:6-10; 74:20-24; 114:15-15:11; Exhibit M at 241:7-242:5 (no familiarity whatsoever with Saint Thomas Hospital formulary).

16. According to STOPNC's medication errors policy, matters involving inappropriate medication use were overseen by Nurse Schamberg and reported to STOPNC's Medical Executive Committee; none of the members of that committee were employed by any of the Saint Thomas Entities. Exhibit M at 230:4-232:6.

17. At no point did Nurse Schamberg or Dr. Culclasure seek the advice of STOPNC's board or any board member regarding the decision to purchase medicine from NECC. Exhibit N at 56:15-23; Exhibit M at 78:13-20; *see also* Exhibit L at 120:7-121:3; Exhibit B at 113:9-16. Dr. Culclasure testified that he never consulted with any pharmacist when making the decision to start purchasing MPA from NECC. Exhibit L at 120:7-9. He stated that he did not even know who Hospital's pharmacy director was. *Id.* at 202:15-23; *see also* Exhibit M 188:17-19 (Nurse Schamberg testifying that she did not recall ever talking with the Saint Thomas Hospital pharmacy director). The Saint Thomas Entities did not know that STOPNC was purchasing from NECC prior to the outbreak. Exhibit B at 114:8-22.

18. The Director of Pharmacy at Hospital at the time, Marty Kelvas, testified that he never consulted with STOPNC about compounding pharmacies in general or NECC in particular and was unaware of anyone in his department having any such consultation with STOPNC. Exhibit P at 179:23-180:13; *see also* Exhibit O at 63:23-64:3; 115:5-13; 116:2-10; Exhibit G at 155:15-17. Mr. Kelvas further testified that there was a "line [] drawn in the sand," Exhibit P at 120:1-12, between the for-profit ventures (including STOPNC) and the not-for-profit hospitals

(including Hospital): “Our contracts were basically for the nonprofit side of the business. As far as any for-profit ventures, that’s a whole different class of trade. We had nothing to do with them.” Exhibit P at 65:23-66:1; *see also id.* 65:6-66:17 & 68:1-10 (context for the answer). The decision by Nurse Schamberg and Dr. Culclasure to purchase NECC-compounded MPA was never brought to the attention of the STOPNC board before the meningitis outbreak. Exhibit B at 113:23-114:7. In fact, there is no evidence that any of the STOPNC board members appointed by Network—or any other employee of the Saint Thomas Entities—was aware that STOPNC was purchasing products from a compounding pharmacy, including NECC. *Id.* at 114:18-22.

19. It is the corporate policy of Health to have written agreements for service arrangements between its affiliates and other entities. Exhibit C at 95:15-19. Health has a single-services agreement with STOPNC through which it provided non-exclusive assistance with managed-care contracts in exchange for \$3,500/year. Services Agreement (Jan. 1, 2004) (“Managed Care Services Agreement”), attached as Exhibit Q; Exhibit E at 98:17-23; 99:12-23. That is the only agreement between those two parties, and there is no evidence of any other involvement by Health in the daily operations of STOPNC. Exhibit E at 49:16-20; 58:15-18; 70:12-14; *id.* at 123:24 (Health’s CEO, when asked why he had never been to the STOPNC facility: “We don’t own or operate [STOPNC] . . . .”); *see also* Exhibit G at 101:21-24.

20. Hospital also has a written agreement to provide certain fee-based services—accounting, food services, and instrument sterilization—to STOPNC, all of which are defined in an agreement. Services Agreement (Sept. 18, 2000), attached as Exhibit R; *see also* Exhibit E at 102:5-107:4; 109:23-110:24; 111:20-112:21.

21. Plaintiffs have attempted to provide additional specifics in their contention interrogatory responses, but have not amended the complaints that contain the direct-liability

allegations. *See, e.g., Plaintiffs' Second Supplemental Response to Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; and Debra V. Schamberg, R.N, First Interrogatories and Requests for Production of Documents Propounded to the Plaintiffs* (Sept. 29, 2015), attached as Exhibit S, First Supplemental Answer to Interrogatory 13.



Dated March 15, 2016

SAINT THOMAS WEST HOSPITAL,  
FORMERLY KNOWN AS ST. THOMAS  
HOSPITAL, SAINT THOMAS  
NETWORK, AND SAINT THOMAS  
HEALTH

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\*Appearing *Pro Hac Vice*

**CERTIFICATE OF SERVICE**

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 15th day of March, 2016.

/s/ Sarah P. Kelly  
SARAH P. KELLY